

**EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION**

**EFFICACY REVIEW - II**

**ANTIMICROBIAL PROGRAM BRANCH**

EPA Reg. No. or File Symbol 1677-129

EPA Petition or EUP No. None

Date Division Received 11-29-93

Type Product FCS Sanitizer/Hospital Disinfectant/Sterilant

MRID No (s) 430265-01 to 430265-09

Product Manager PM 31 (Lee)

Product Name OXONIA ACTIVE

Company Name Ecolab Inc.

202.0 **Recommendations**

202.2 **Efficacy Supported by the Data:**

- A. The submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-01 and 430265-04) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 6 hours at 20°C.
- B. Also, the submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-02, 430265-05 and 430265-6) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 15 minutes at 50°C.

The submitted additional confirmatory AOAC Sporocidal Test data (MRID No. 430265-07) are also acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 20 minutes at 50°C.

- C. Also, the submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-03 and 430265-08) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 2.5 minutes at 80°C.

The submitted additional confirmatory AOAC Sporocidal Test data (MRID No. 430265-09) are also acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 5 minutes at 80°C.

203.0 **Labeling:**

Include a disclaimer statement, "Not to be used on critical or semicritical items as a sterilant or as a high level disinfectant". (see next page for the required text of the completed disclaimer statement)

No other adverse comments.

J.G.V. Head,  
EEMS  
3/11/94

"This product is not to be used (as a terminal sterilant/high level disinfectant) on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

204.0

**For Your Information:**

Please be advised that Environmental Protection Agency will retest your product to confirm your efficacy claim as a sterilant prior to allowing this new sterilization claim on the label.